

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Raymond J. Bergeron, Jr.

Application No.: 10/645,348

Group Art Unit: 1614

Filed: August 21, 2003

Examiner: Not Yet Assigned

Confirmation No.: 7060

Title: Antioxidant and Radical Scavenging Activity of Synthetic Analogs of Desferrithiocin

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
6/18/04 Date	<i>Rachel Meehan</i> Signature
RACHEL MEEHAN Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references (AN, AO, AR2-AZ2, AR3-AZ3 & AR4-AT4) are enclosed.
  - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for reference AO under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☒ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

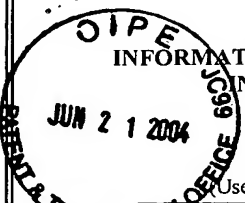
Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Jesse A. Fecker  
Jesse A. Fecker  
Registration No.: 52,883  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 6-15-04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2134.2009-001		APPLICATION NO. 10/645,348	
 <p><b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b></p> <p>May 28, 2004</p> <p>(Use several sheets if necessary)</p>		FIRST NAMED INVENTOR Raymond J. Bergeron, Jr.		FILING DATE August 21, 2003	
		EXAMINER Not Yet Assigned		CONFIRMATION NO. 7060	

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AC	3,274,207	09-20-1966	Kollonitsch
	AD	4,457,935	07-03-1984	Iwao <i>et al.</i>
	AE	4,558,059	12-10-1985	Kawasaki <i>et al.</i>
	AF	4,736,060	04-05-1988	Tomuro <i>et al.</i>
	AF	4,914,208	04-03-1990	Jakob <i>et al.</i>
	AH	5,057,494	10-15-1991	Sheffield
	AI	5,192,781	03-09-1993	Bru-Magniez <i>et al.</i>
	AJ	5,403,834	04-04-1995	Malfroy-Camine <i>et al.</i>
	AK	5,696,109	12-09-1997	Malfroy-Camine <i>et al.</i>
	AA2	5,840,739	11-24-1998	Bergeron, Jr.
	AB2	6,080,764	06-27-2000	Chihiro <i>et al.</i>
	AC2	6,083,966	07-04-2000	Bergeron, Jr.
	AD2	6,147,070	11-14-2000	Facchini
	AE2	6,159,983	12-12-2000	Bergeron, Jr.
	AF2	US 6,372,912 B1	04-16-2002	Döring <i>et al.</i>
	AG2	US 2002/0049316 A1	04-25-2002	Halbert <i>et al.</i>

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AN	WO 00/16763	03-30-2000	University of Florida Research Foundation, Inc., <i>et al.</i>		
	AO	WO 01/27119 A3	04-19-2001	Gruenenthal GMBH		

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR2	Bergeron, R.J., <i>et al.</i> , "A Comparative Study of the Iron-Clearing Properties of Desferrithiocin Analogues With Desferrioxamine B in a <i>Cebus</i> Monkey Model," <i>Blood</i> , 81(8):2166-2173, (1993).
--	-----	---

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED  <b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 28, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2134.2009-001		APPLICATION NO. 10/645,348	
	FIRST NAMED INVENTOR Raymond J. Bergeron, Jr.		FILING DATE August 21, 2003	
	EXAMINER Not Yet Assigned	CONFIRMATION NO. 7060	GROUP 1614	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AS2	Bergeron, R.J., <i>et al.</i> , "An Investigation of Desferrithiocin Metabolism," <i>J. Med. Chem.</i> , 37(18):2889-2895, (1994).	
AT2	Bergeron, R.J., <i>et al.</i> , "Desazadesmethyldesferrithiocin Analogues as Orally Effective Iron Chelators," <i>J. Med. Chem.</i> , 42(1):95-108, (1999).	
AU2	Bergeron, R.J., <i>et al.</i> , "Effects of C-4 Stereochemistry and C-4' Hydroxylation on the Iron Clearing Efficiency and Toxicity of Desferrithiocin Analogues," <i>J. Med. Chem.</i> , 42(13):2432-2440, (1999).	
AV2	Bergeron, R.J., <i>et al.</i> , "Evaluation of the Desferrithiocin Pharmacophore as a Vector for Hydroxamates," <i>J. Med. Chem.</i> , 42(15):2881-2886, (1999).	
AW2	Bergeron, R.J., <i>et al.</i> , "Evaluation of Desferrithiocin and Its Synthetic Analogues as Orally Effective Iron Chelators," <i>J. Med. Chem.</i> , 34(7):2072-2078, (1991).	
AX2	Bergeron, R.J., <i>et al.</i> , "Pharmacokinetics of Orally Administered Desferrithiocin Analogs in <i>Cebus Apella</i> Primates," <i>Drug Metabolism and Disposition</i> , 27(12):1496-1498, (1999).	
AY2	Bergeron, R.J., <i>et al.</i> , "Synthesis and Biological Evaluation of Naphthyldesferrithiocin Iron Chelators," <i>J. Med. Chem.</i> , 39(8):1575-1581, (1996).	
AZ2	Bergeron, R.J., <i>et al.</i> , "The Origin of the Differences in (R)- and (S)-Desmethyldesferrithiocin: Iron-Clearing Properties," <i>Annals of the NY Academy of Sciences</i> , 850:202-216, (1998).	
AR3	Bierer, B.E. and Nathan D.G., "The Effect of Desferrithiocin, an Oral Iron Chelator, on T-Cell Function," <i>Blood</i> , 76(10):2052-2059, (1990).	
AS3	Cragg, L., <i>et al.</i> , "The Iron Chelator L1 Potentiates Oxidative DNA Damage in Iron-Loaded Liver Cells," <i>Blood</i> , 92(2):632-638, (1998).	
AT3	Dean, R.T. and Nicholson, P., "The Action of Nine Chelators on Iron-Dependent Radical Damage," <i>Free Rad. Res.</i> , 20(2):83-101, (1994).	
AU3	Denicola, A., <i>et al.</i> , "Desferrioxamine Inhibition of the Hydroxyl Radical-Like Reactivity of Peroxynitrite: Role of the Hydroxamic Groups," <i>Free Rad. Biol. Med.</i> , 19(1):11-19, (1995).	
AV3	Green, E.S.R., <i>et al.</i> , "The Efficacy of Monohydroxamates as Free Radical Scavenging Agents Compared with Di- and Trihydroxamates," <i>Biochem. Pharm.</i> , 45(2):357-366, (1993).	

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED  <b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 28, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2134.2009-001		APPLICATION NO. 10/645,348	
	FIRST NAMED INVENTOR Raymond J. Bergeron, Jr.		FILING DATE August 21, 2003	
	EXAMINER Not Yet Assigned	CONFIRMATION NO. 7060	GROUP 1614	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AW3	Grisham, M.B., <i>et al.</i> , "Prooxidant Properties of 5-Aminosalicylic Acid: Possible Mechanism for Its Adverse Side Effects," <i>Digestive Diseases and Sciences</i> , 37(9):1383-1389, (1992).
	AX3	Re, R., <i>et al.</i> , "Antioxidant Activity Applying an Improved ABTS Radical Cation Decolorization Assay," <i>Free Rad. Biol. Med.</i> , 26(9/10):1231-1237, (1999).
	AY3	Samuni, A.M., <i>et al.</i> , "Multifunctional Antioxidant Activity of HBED Iron Chelator," <i>Free Rad. Biol. Med.</i> , 30(2):170-177, (2001).
	AZ3	Whitley, W.D., <i>et al.</i> , "Iron Chelation Suppresses Mononuclear Cell Activation, Modifies Lymphocyte Migration Patterns, and Prolongs Rat Cardiac Allograft Survival in Rats," <i>Transplantation</i> , 56(5):1182-1188, (1993).
	AR4	Halliwell, Barry, "Protection Against Tissue Damage in vivo By Desferrioxamine: What Is Its Mechanism Of Action?" <i>Free Radical Biology &amp; Medicine</i> , 7:645-651 (1989).
	AS4	Halliwell, Barry, "Iron, Oxidative Damage, and Chelating Agents," In <i>The Development of Iron Chelators for Clinical Use</i> , (CRC Press, Inc.), pp. 33-56 (1994).
	AT4	Kicic, A., <i>et al.</i> , "Desferrithiocin is a more potent antineoplastic agent than desferrioxamine," <i>British Journal of Pharmacology</i> , 135:1393-1402 (2002).

EXAMINER	DATE CONSIDERED
----------	-----------------